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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,801	09/19/2001	Rajneesh Taneja	ABB01259P00210US (6842.US)	1051
7590 10/31/2008 TAP Pharmaceutical Products, Inc. Attention: Mark J. Buonaiuto 675 North Field Drive Lake Forest, IL 60045			EXAMINER SHEIKH, HUMERA N	
			ART UNIT 1615	PAPER NUMBER
			MAIL DATE 10/31/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/955,801	<b>Applicant(s)</b> TANEJA ET AL.	
	<b>Examiner</b> Humera N. Sheikh	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-17 and 19-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-17 and 19-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### **Status of the Application**

Receipt of the Response after Non-Final Office Action, Applicant's Arguments/Remarks, and the request for extension of time (3 months-granted), all filed 08/06/08 is acknowledged.

Claims 1, 3-17 and 19-21 are pending in this action. No amendments to the claims have been made herein. Claims 2 and 18 have been previously cancelled. Claims 1, 3-17 and 19-21 remain rejected.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claims 1, 3-17 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips (U.S. Pat. No. 6,489,346).**

**Phillips ('346)** teaches a non-enteric coated solid pharmaceutical composition comprising a non-enteric coated proton pump inhibitor in a pharmaceutically acceptable carrier and at least one buffering agent and a method for treating acid-related gastrointestinal disorders comprising administering to a patient the non-enteric coated solid pharmaceutical composition. The pharmaceutically acceptable carrier comprises a bicarbonate salt of a Group IA metal and a carbonate salt of a Group IA metal (see Abstract; Claims); (col. 11, lines 36-44); (col. 13, line 47 – col. 14, line 26).

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Phillips teaches that mixtures of the buffering agents can be utilized (column 13, lines 47-53). Suitable buffering agents disclosed include sodium bicarbonate, potassium bicarbonate, magnesium hydroxide, aluminum hydroxide, aluminum hydroxide/sodium bicarbonate co-precipitate, sodium carbonate and calcium carbonate (see col. 13, line 63 – col. 14, line 14); (col. 17, lines 58-60).

The non-enteric proton pump inhibitors include a substituted benzimidazole of lansoprazole or an enantiomer, isomer, derivative, free base or salts thereof (see Abstract).

While Phillips does not explicitly teach the instant ratio of the water-soluble acid neutralizer: water-insoluble acid neutralizer being about 1:20 to about 10:1, the determination of suitable or effective ratios is within the level of one of ordinary skill in the art, obtained by routine or manipulative experimentation to obtain optimal results, as these are variable parameters attainable within the art. Applicants have not demonstrated any superior or unexpected results, which accrue from the instant ratios claimed. The prior art vividly teaches a solid non-enterically coated proton pump inhibitor pharmaceutical composition in combination with water-soluble as well as water-insoluble acid neutralizers, that function to protect the PPI from acid degradation and provides for the beneficially effective treatment of acid-related gastrointestinal disorders. Hence, the art suggests use of the same ingredients, being used in the same art area to achieve the same results.

The instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art, given the teachings of Phillips.

\* \* \* \* \*

***Pertinent Art:***

The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure:

- US Patent No. 4,786,505 (Lovgren *et al.*) 11-1988

\* \* \* \* \*

***Response to Arguments***

Applicant's arguments filed 08/06/08 have been fully considered but were not found to be persuasive.

- **35 U.S.C. §103(a) rejection of claims 1, 3-17 and 19-21 over Phillips (US 6,489,346):**

(1) Applicant argued, "The specific combination and ratios described by the present invention would not have been obvious to one of ordinary skill in the art even in view of Phillips, and that this is not a case of routine optimization. In particular, Applicants note that the specification specifically provides "[i]t has been surprisingly and unexpectedly discovered that the combination of acid neutralizers is capable of increasing the pH to a greater extent and maintaining the pH at increased levels for a great timer period than either of the acid neutralizers alone." (See, page 5 of specification)."

Applicant's arguments have been fully considered but were not deemed persuasive. Applicant's arguments do not establish the scope of claims being presented. The claims are entirely silent with respect to any particular pH levels, silent with respect to increasing pH levels and even silent with regards to maintaining pH levels and further, silent with reference to any

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specific duration of time for which the pH levels should be maintained. Thus, Applicant's arguments are not reflective of and do not parallel the scope of claims presented.

(2) Applicant argued, "In contrast, Phillips makes no reference to the specific combination or ratios provided within the specification of the present invention, nor does it discuss the desired effects and surprising results that have been discovered through using a combination of acid neutralizers being selected from water-soluble and water-insoluble acid neutralizers."

These arguments were not convincing. As noted by Applicant, Phillips teaches that "at least one buffering agent" preferably sodium bicarbonate, and many other weak and strong bases (and mixtures thereof) maybe used. The reference is clearly suggestive of and teaches a composition that provides for a pharmaceutically acceptable carrier, a bicarbonate salt of a Group IA metal and a carbonate salt of a Group IA metal, useful for treating acid-related gastrointestinal disorders. The art is well aware of employing a combination comprised of both a Group IA bicarbonate and carbonate metal salt, as evidenced by the teachings of Phillips. With regards to the instant ratios, it remains the position of the Examiner that this would be a routine-optimized variable and would only establish a difference in degree and not of kind.

(3) Applicant argued, "Phillips provides a laundry list of potential buffering agents, but does not specifically indicate that a specific combination of water-soluble and water-insoluble acid neutralizers is desirable...Phillips instead just states that a combination of buffers may be used. Phillips fails to appreciate or recognize that the specific combinations as claimed in the present invention provide surprising and unexpected results by increasing the pH to a greater

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extent and maintaining the pH at increased levels for a greater time period than either of the acid neutralizers alone.”

These arguments were not rendered persuasive. The Examiner notes that the instant independent claims are entirely generic in terms of any particular or specified water-soluble and water in-soluble neutralizers. With regards to the selective neutralizers of the dependent claims, the reference vividly demonstrates compositions comprising both a bicarbonate salt of a Group IA metal and a carbonate salt of a Group IA metal and goes even further by stating that ‘mixtures of the buffering agents can be utilized’. The buffering agents disclosed by Phillip are the same as those being claimed (i.e., sodium bicarbonate, potassium bicarbonate, magnesium hydroxide, aluminum hydroxide, etc.). Thus it cannot be seen as to how the teachings of the reference are so far from the instant invention as to render them non-obvious, particularly when the reference teaches the same buffering agents and notably teaches that mixtures of the buffering agents can be used. Moreover, the unexpected results argued by Applicant (increasing/maintaining pH levels) would also be possible using the composition of Phillips, since Phillips teaches use of the same ingredients, being used in the same art area. Thus, it would be expected that the same beneficial results would be imparted thereby based on Phillips, who employs the same elements. Furthermore, as noted above, the claims are silent with respect to any reference pointing to desired pH levels or increasing and/or maintaining pH levels, nor any time duration for which the pH levels should be maintained.

(4) Regarding Applicant’s argument that “Phillips does not the desired effects and surprising results discovered using a combination of acid neutralizers”, the Examiner points out that “One of ordinary skill in the art need not see the identical problem addressed in a prior art

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reference to be motivated to apply its teachings.”;< In re Linter, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972).

Lastly, the issue is whether one of ordinary skill in the art would be aware of the benefits of providing for a non-enterically coated proton pump inhibiting composition containing both a water-soluble and water-insoluble acid neutralizer to achieve therapeutically-effective results. This procedure is clearly suggested in the cited art of record.

The 35 U.S.C. §103(a) rejection has been maintained.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

--No claims are allowed at this time.



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### **Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday-Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1615

*hns*

October 29, 2008

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